

### **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

#### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-4, 7, 10-12, and 15-21 are currently under consideration. Claims 1, 3, and 4 are amended, and claims 15-21 are newly added without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

The amendment to claims 1, 3 and 4 clarify the claimed invention. Support for newly added claims 15-21 can be found, for instance, in Example 10 and previously presented claims 1-4 and 10-12. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled.

#### **II. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME**

##### **Indefiniteness**

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action contends that claim 1 is vague because the term *Canavalia gladiata* is misspelled as *Cavalia gladiata*.

Applicants note that claim 1 is amended to correct the misspelling, thereby obviating the rejection.

##### **Enablement**

Claims 1, 3, and 4 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. This rejection is traversed.

Applicants draw attention to amended claims 1, 3, and 4, which are directed to a topical formulation for treating acne, and assert that the instant claims are enabled by the specification.

Notably, the Office Action concedes that the specification is "enabled for a topical formulation for treating acne comprising extracts obtained from *Canavalia gladiata*, *Biota orientalis*, and *Coptis chinensis* (page 4, 5<sup>th</sup> paragraph of Office Action).

Indeed, the specification provides ample guidance for practicing the present invention, including description of the components of the formulation (see page 4, line 23 – page 6, line 4), preparation of these components (page 6, lines 5-16), and preparation of the formulation (page 6, line 17 – page 7, line 12). In addition, the working examples provide further guidance for preparing the components of the formulation (Example 1), and testing the formulation for its inhibitory effect on 5 $\alpha$ -reductase (Example 2), its antimicrobial activity against an acne pathogen (Example 3), its inhibitory activity to hypercornification (Example 4), its anti-inflammatory effects (Example 5), its alleviatory effect on comedo (Example 6), and its general effects on human skin (Example 10).

Therefore, the instant claims are enabled by the specification.

Reconsideration and withdrawal of all rejections under Section 112 are requested.

### **III. THE REJECTION UNDER 35 U.S.C. § 102 IS OVERCOME**

Claim 1 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Yamamoto (JP 409143087). The Office Action contends that Yamamoto relates to a topical formulation comprising an extract obtained from *Canavalia gladiata*. The rejection is traversed.

Applicants argue that claim 1 is directed to a topical formulation for treating acne, while Yamamoto relates to a preparation for improving skin roughness; therefore, Yamamoto does not anticipate the claim invention. Applicants note that the determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. In this case, the embodiment of the invention recited in claim 1 is a formulation which Applicants intend to use as a treatment for acne. The preamble of claim 1 breathes life and meaning into the claim.

Thus, Applicants assert that Yamamoto fails to anticipate the instant invention, and requests for reconsideration and withdrawal of the Section 102 rejection.

#### IV. THE REJECTION UNDER 35 U.S.C. § 103 IS OVERCOME

Claims 1-4, 7, and 10-12 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wakasaya (JP 2001089346) in view of Sugihara *et al.* (JP 355127317) and Basu *et al.* (U.S. Publication No. 20020025348). According to the Office Action, Wakasaya relates to a formulation comprising an extract obtained from the elected species of *Canavalia gladiata*, while Sugihara *et al.* allegedly relates to *Biota orientalis* extracts administered for treating inflammation disorders. Basu *et al.* allegedly relates to *Coptis chinensis* extracts externally administered to treat inflammation disorders. The Office Action alleges that it would have been obvious to one of ordinary skill in the art to modify the teachings of Wakasaya's formulation to include the claimed active ingredients of *Biota orientalis* and *Coptis chinensis* as taught by Sugihara *et al.* and Basu *et al.*, respectively. The rejection is traversed.

In response, Applicants argue that one skilled in the art would not expect to successfully arrive at the present invention as recited in claims 1, 2, 7, and 10 in view of these references. As noted above, these claims relate to the treatment of acne, and the specification explicitly recites that such treatment occurs through "antimicrobial activity against acne-causing bacteria, *Propionibacterium acnes*, inhibition of excess production of sebum by inhibition of 5 $\alpha$ -reductase, inhibition of comedo formation, keratolysis and anti-inflammatory action" (see paragraph beginning at page 4, line 23). There is no teaching or suggestion in Wakasaya or Sugihara *et al.* that their compositions can treat acne or has antimicrobial activity against acne-causing bacteria, *Propionibacterium acnes*, can inhibit excess production of sebum by inhibition of 5 $\alpha$ -reductase, or can inhibit comedo formation. Thus, there would be no expectation that the compositions of Wakasaya or Sugihara *et al.* can treat acne.

In addition, the skilled artisan would not arrive at the invention as recited in claims 3, 4, 11, and 12, since these compositions are not taught or suggested in Wakasaya, Sugihara *et al.*, and Basu *et al.*, alone or combined.

Furthermore, according to the abstract, Sugihara *et al.* relates to a composition comprised of extracts from one or two or more crude drugs selected from *Drynaria fortunei*, leaves of *Biota orientalis*, *Sanguisorba officinalis* Linn. *Var. carnea* Regel, lotus roots, leaves of *Artemisia princeps* PAM., leaves of *Juniperus communis* L., leaves of Sugis, roots of *Panax notoginseng* Burkill, Lycium bark, and roots of *Rubia akane* Nakai. Therefore, in order to arrive at the invention of instant claims 1-4, 7, or 10-12, one skilled in the art would have to choose *Biota*

*orientalis* from among the 10 extracts recited in Sugihara *et al.* with the desired expectation. Clearly, there is no guidance in Sugihara *et al.* that would lead the skilled artisan to choose *Biota orientalis* to arrive at the invention of claims 1, 2, 7, and 10, or would lead the skilled artisan to choose *Biota orientalis* to combine with the formulation of Wakasaya in order to arrive at the invention of claims 3, 4, 11, and 12.

Similarly Basu *et al.* relates to a composition comprising one or more of the following herbs: Hou Po (*Magnoliae officinalis*), Huang Bai, which is also often referred to as Huang Bo (*Phellodendron chinense*), Huang Lian (*Coptis chinensis*), Huo Xiang (*Agastaches rugosa*), Pao Jiang (*Zingiberis officinalis*), Qin Pi (*Fraxinus rynchophylla*), and Zhi Gan Cao (*Glycyrrhizae inflata*). In order to arrive at the invention of instant claims 3, 4, 11, and 12, one skilled in the art would have been expected to choose Huang Bai (*Coptis chinensis*) from among the 7 herbs recited in Basu *et al.* with the desired expectation. There is no guidance in Basu *et al.* that would lead the skilled artisan to choose *Coptis chinensis* to combine with the formulation of Wakasaya and with *Biota orientalis* of Sugihara *et al.* in order to arrive at the invention of claims 3, 4, 11, and 12.

Furthermore, Applicants assert that there is no motivation to combine Wakasaya with the other cited references in order to arrive at the invention of claims 3, 4, 11, and 12. Wakasaya relates to a mouth composition used for the prevention and curing of inflammation in the mouth. In contrast, Basu *et al.* relates to a composition for treating Inflammatory Bowel Disease, while Sugihara *et al.* relates to a composition for treating skin inflammations due to the irritation of ultraviolet rays. It is well known in the art that compositions designed for internal administration, *e.g.*, in Wakasaya and Basu *et al.*, are greatly different than compositions designed for external administration *e.g.*, in Sugihara *et al.* Hence, there would be no motivation to incorporate *Biota orientalis* used for topical application in Sugihara *et al.* into the oral formulation of Wakasaya, as suggested by the Office Action.

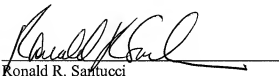
Hence, the instant invention is not unpatentable in view of the cited references. Accordingly, reconsideration and withdrawal of the rejection under Section 103 are requested.

**CONCLUSION**

This application is in condition for allowance. Favourable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favourably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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